DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0142]

21 CFR Chapter I

Removal of Delegations of Authority and Conforming Changes to Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing this final rule to amend the regulations by removing the delegations of authority, to update the regulations to reflect the agency's organization, and to make other conforming changes. Because FDA makes information on delegations of authority available on FDA's Internet Web site, the regulations on delegations of authority are no longer necessary. The availability of the information on delegations of authority through the agency's Web site provides the public with more current and up-to-date information.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Donna G. Page, Management Programs and Analysis Branch (HFA–340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4816; or

Rudy Guillen, Management Programs and Analysis Branch (HFA–340), 5600 Fishers Lane, Rockville, MD 20857, 301–827–4806.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing this final rule to amend its regulations by removing the delegations of authority previously published in part 5 (21 CFR part 5) and to update the organizational information in part 5. The delegation of authority information is now available on the Internet at *http://www.fda.gov/smg/default.htm*. Attached to this final rule is an appendix that cross-references the previously used CFR citations to the Internet-based system. The agency last updated part 5 in a final rule published on June 8, 2001 (66 FR 30992). In the preamble of that final rule, FDA stated its plan to move to an Internet-based system and remove the delegations of authority from part 5. The use of an Internet-based system allows FDA to provide more current and up-to-date information to the public on delegations of authority.

The agency has also made conforming changes to several other parts to remove the references to the delegations of authority in part 5 and to make other conforming changes. The agency has made these changes to the following regulations: 21 CFR 7.45(a), 10.1(a), 10.3(a), 16.26(a), 16.40, 25.5(b)(5), 25.40(e), 25.45(a), 500.80(a), and 1002.3. Additionally, the agency has updated the references to part 5, subpart M in the following regulations: 21 CFR 21.43(a)(2), 106.120(b), 107.50(e)(2), 107.230(e), 107.240(b) and (c)(1), 107.250, 203.11(a), and 800.55(g)(4).

The portion of this final rule removing the part 5 delegations of authority and updating the organizational information in part 5, subpart M is a rule of agency organization, procedure, or practice. FDA is issuing these provisions as a final rule without publishing a general notice of proposed rulemaking because such notice is not required for rules of agency organization, procedure, or practice under 5 U.S.C. 553(b)(3)(A). For the conforming changes to the

other regulations, the agency finds good cause under 5 U.S.C. 553(b)(3)(B) to dispense with prior notice and comment, and good cause under 5 U.S.C. 553(d)(3) to make these conforming changes effective less than 30 days after publication because such notice and comment and delayed effective date are unnecessary and contrary to the public interest. As discussed previously, these conforming changes merely remove references to part 5, update the references to part 5, subpart M, and make other minor conforming changes. These changes do not result in any substantive change to the regulations.

II. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the principles identified in the Executive order. In addition, the final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule simply removes the part 5 delegations of authority, updates the organizational information, and makes conforming changes to other regulations, it does not impose any additional costs on industry. Consequently, the agency certifies that the final rule will not have a significant economic

impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure year by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year (adjusted annually for inflation). The current threshold after adjustment for inflation is $112.3 million. As stated previously, this final rule does not impose any additional costs on industry. Therefore, this final rule will not result in any 1-year expenditure that would meet or exceed this amount.

III. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

IV. Environmental Impact

FDA has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly the agency has concluded that the rule does not

contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

List of Subjects

21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

21 CFR Part 7

Administrative practice and procedure, Consumer protection, Reporting and recordkeeping requirements.

21 CFR Part 10

Administrative practice and procedure, News media.

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 21

Privacy.

21 CFR Part 25

Environmental impact statements, Foreign relations, Reporting and recordkeeping requirements.

21 CFR Part 106

Food grades and standards, Infants and children, Nutrition, Reporting and recordkeeping requirements.

21 CFR Part 107

Food labeling, Infants and children, Nutrition, Reporting and recordkeeping requirements, Signs and symbols.

21 CFR Part 203

Labeling, Prescription drugs, Reporting and recordkeeping requirements, Warehouses.

21 CFR Part 500

Animal drugs, Animal feeds, Cancer, Labeling, Packaging and containers, Polychlorinated biphenyls (PCBs).

21 CFR Part 800

Administrative practice and procedure, Medical devices, Ophthalmic goods and services, Packaging and containers, Reporting and recordkeeping requirements.

21 CFR Part 1002

Electronic products, Radiation protection, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority of the Commissioner of Food and Drugs, 21 CFR Chapter I is amended as follows:

■ 1. Part 5 is revised in its entirety to read as follows:

PART 5—ORGANIZATION

Subparts A–L [Reserved]

Subpart M—Organization

Sec.

5.1100 Headquarters.

5.1105 Chief Counsel, Food and Drug Administration.

5.1110 FDA Public Information Offices.

Authority: 5 U.S.C. 552; 21 U.S.C. 301–397.

Subparts A–L [Reserved]

Subpart M—Organization

§ 5.1100 Headquarters.

The central organization of the Food and Drug Administration consists of the following:

OFFICE OF THE COMMISSIONER.[1]

Office of the Chief Counsel.[2]

Office of Equal Employment Opportunity and Diversity.

Office of the Administrative Law Judge.

Office of External Relations.

Office of Executive Secretariat.

Office of Public Affairs.

Office of the Ombudsman.

Office of Special Health Issues.

Office of Policy and Planning.

[1] Mailing address: 5600 Fishers Lane, Rockville, MD 20857.

[2] The Office of the Chief Counsel (also known as the Food and Drug Division, Office of the General Counsel, Department of Health and Human Services), while administratively within the Office of the Commissioner, is part of the Office of the General Counsel of the Department of Health and Human Services.

Office of Policy.

Office of Planning.

Office of Management.

Office of the Chief Information Officer.

Office of Financial Management.

Office of Shared Services.[3]

Office of Management Programs.

Office of Executive Operations.

Office of Science and Health Coordination.

Office of Orphan Products Development.

Office of Women's Health.

Office of International Activities and Strategic Initiatives.

Office of International Programs.

Office of Pediatric Therapeutics.

Office of Combination Products.

Office of Legislation.

Office of Crisis Management.

Office of Emergency Operations.

Office of Security Operations, Policy and Planning.

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH.[4]

Office of the Center Director.

Scientific Advisors and Consultants Staff.

Equal Employment Opportunity and Workforce Diversity Staff.

Quality Assurance Staff.

Regulations and Policy Staff.

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[3] Mailing address: 5630 Fishers Lane, Rockville, MD 20852.
[4] Mailing address: 1401 Rockville Pike, Rockville, MD 20852–1448.

Veterinary Services Staff.

Office of Management.

Regulatory Information Management Staff.

Division of Planning, Evaluation, and Budget.

Division of Management Services.

Office of Compliance and Biologics Quality.

Division of Case Management.

Division of Manufacturing and Product Quality.

Division of Inspections and Surveillance.

Office of Blood Research and Review.

Policy and Publications Staff.

Division of Emerging and Transfusion Transmitted Diseases.

Division of Hematology.

Division of Blood Applications.

Office of Vaccines Research and Review.

Analytical Chemistry Staff.

Standards and Testing Staff.

Division of Bacterial, Parasitic, and Allergenic Products.

Division of Viral Products.

Division of Vaccines and Related Products Applications.

Office of Communication, Training, and Manufacturers Assistance.

Division of Disclosure and Oversight Management.

Division of Manufacturers Assistance and Training.

Division of Communication and Consumer Affairs.

Office of Biostatistics and Epidemiology.

Division of Biostatistics.

Division of Epidemiology.

Office of Information Management.

Division of Information Operations.

Division of Information Development.

Office of Cellular, Tissue, and Gene Therapies.

Division of Cell and Gene Therapies.

Division of Clinical Evaluation and Pharmacology/Toxicology Review.

Division of Human Tissues.

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION.[5]

Office of the Center Director.

Food Safety Staff.

Office of Science.

Quality Assurance Staff.

CFSAN Staff College.

Microbial Research and Risk Assessment Staff.

JIFSAN Liaison Staff.

CFSAN Food Advisory Committee Staff.

Office of Applied Research and Safety Assessment.

Muirkirk Technical Operations Staff.

Division of Molecular Biology.

Division of Virulence Assessment.

Division of Toxicology.

Office of Regulations and Policy.

Regulations Management Staff.

Office of Constituent Operations.

Consumer Education Staff.

International Activities Staff.

[5] Mailing address: 5100 Paint Branch Pkwy., College Park, MD 20740–3835.

Industry Activities Staff.

Office of Management Systems.

Safety Management Staff.

Division of Information Resources Management.

Division of Planning and Financial Resources Management.

Division of Program Support Services.

Office of Operations.

Equal Employment Opportunity Staff.

Executive Operations Staff.

Office of Cosmetics and Colors.

Division of Color Certification and Technology.

Division of Cosmetics and Compliance.

Office of Nutritional Products, Labeling and Dietary Supplements.

Infant Formula and Medical Foods Staff.

Division of Dietary Supplement Programs and Compliance.

Division of Food Labeling, Standards and Compliance.

Division of Nutrition Programs and Labeling.

Division of Research and Applied Technology.

Office of Food Additive Safety.

Division of Petition Review.

Division of Chemistry Research and Environmental Review.

Division of Food Contact Notifications.

Division of Biotechnology and GRAS Notice Review.

Office of Plant and Dairy Foods and Beverages.

Division of Pesticides and Industrial Chemicals.

Division of Natural Products.

Division of Food Processing and Packaging.

Division of Plant Product Safety.

Division of Dairy and Egg Safety.

Division of Risk Assessment.

Division of Microbiological Studies.

Office of Seafood.

Division of Programs and Enforcement Policy.

Division of Science and Applied Technology.

Office of Compliance.

Emergency Coordination and Response Staff.

Division of Enforcement.

Division of Field Programs.

Division of Cooperative Programs.

Office of Scientific Analysis and Support.

CFSAN Adverse Events Reporting System Staff.

Division of General Scientific Support.

Division of Mathematics.

Division of Market Studies.

CENTER FOR DRUG EVALUATION AND RESEARCH.[1]

Office of the Center Director.

Equal Employment Opportunity Staff.

Controlled Substance Staff.

Office of Regulatory Policy.

Division of Regulatory Policy I.

Division of Regulatory Policy II.

Division of Information Disclosure Policy.

Office of Management.[1]

Division of Management and Budget.[1]

Division of Management Services.[1]

Office of Training and Communication.[1]

Division of Training and Development.

Division of Public Affairs.

Division of Drug Information.

Division of Library and Information Services.

Office of Compliance.[1]

Division of Compliance Risk Management and Surveillance.

Division of New Drugs and Labeling Compliance.

Division of Manufacturing and Product Quality.

Office of Information Technology.[1]

Quality Assurance Staff.

Technology Support Services Staff.

Division of Applications Development and Services.

Division of Infrastructure Management and Services.

Office of Medical Policy.[1]

Division of Drug Marketing, Advertising and Communication.[1]

Division of Scientific Investigations.[6]

Office of Pharmacoepidemiology and Statistical Science.

Office of Drug Safety.

Division of Surveillance, Research and Communication Support.

Division of Medication Errors and Technical Support.

Division of Drug Risk Evaluation.

Office of Biostatistics.

Quantitative Methods and Research Staff.

Division of Biometrics I.

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[6] Mailing address: 7520 Standish Pl., Rockville, MD 20855.

Division of Biometrics II.

Division of Biometrics III.

Office of Executive Programs.

Executive Operations Staff.

Quality Assurance Staff.

Advisors and Consultants Staff.[2]

Office of Counter-Terrorism and Pediatric Drug Development.

Division of Counter-Terrorism.

Division of Pediatric Drug Development.

Office of Information Management.

Business Information Staff.

Review Technology Staff.

Division of Records Management.

Office of New Drugs.[1]

Office of Drug Evaluation I.[1]

Division of Cardio-Renal Drug Products.

Division of Neuropharmacological Drug Products.

Division of Oncology Drug Products.

Office of Drug Evaluation II.[1]

Division of Metabolic and Endocrine Drug Products.

Division of Pulmonary and Allergy Drug Products.

Division of Anesthetic, Critical Care and Addiction Drug Products.

Office of Drug Evaluation III.[1]

Division of Gastrointestinal and Coagulation Drug Products.

Division of Medical Imaging and Radiopharmaceutical Drug Products.

Division of Reproductive and Urologic Drug Products.

Office of Drug Evaluation IV. [1]

Division of Anti-Infective Drug Products.

Division of Anti-Viral Drug Products.

Division of Special Pathogen and Immunologic Drug Products.

Office of Drug Evaluation V.

Division of Anti-Inflammatory, Analgesic and Ophthalmologic Drug Products.

Division of Dermatologic and Dental Drug Products.

Division of Over-The-Counter Drug Products.

Office of Drug Evaluation VI.

Division of Therapeutic Biological Oncology Products.

Division of Therapeutic Biological Internal Medicine Products.

Division of Review Management and Policy.

Office of Pharmaceutical Science.[1]

Quality Implementation Staff.[1]

Operations Staff.[1]

Informatics and Computational Safety Analysis Staff.

Office of Clinical Pharmacology and Biopharmaceutics.

Pharmacometrics Staff.

Division of Pharmaceutical Evaluation I.[1]

Division of Pharmaceutical Evaluation II.[1]

Division of Pharmaceutical Evaluation III.[1]

Office of Generic Drugs.[6]

Division of Bioequivalence.

Division of Chemistry I.

Division of Chemistry II.

Division of Labeling and Program Support.

Division of Chemistry III.

Office of New Drug Chemistry.[1]

Division of New Drug Chemistry I.[1]

Division of New Drug Chemistry II.[1]

Division of New Drug Chemistry III.[1]

Office of Testing and Research.[1]

Laboratory of Clinical Pharmacology.[7]

Division of Applied Pharmacology Research.[8]

Division of Pharmaceutical Analysis.[9]

Division of Product Quality Research.[1]

Office of Biotechnology Products.

Division of Monoclonal Antibodies.

Division of Therapeutic Protein.

OFFICE OF REGULATORY AFFAIRS.[1]

Equal Employment Opportunity Staff.

Office of Resource Management.

Strategic Initiatives Staff.

Division of Planning, Evaluation, and Management.

Division of Human Resource Development.

Division of Management Operations.

Division of Personnel Operations.

Office of Information Technology.

Office of Enforcement.

Division of Compliance Management and Operations.

Division of Compliance Policy.

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[7] Mailing address: Four Research Ct., Rockville, MD 20850.
[8] Mailing address: 8301 Muirkirk Rd., Laurel, MD 20708.
[9] Mailing address: 1114 Market St., St. Louis, MO 63101.

Division of Compliance Information and Quality Assurance.

Office of Regional Operations.

Division of Federal-State Relations.

Division of Field Science.

Division of Import Operations and Policy.

Division of Field Investigations.

Office of Criminal Investigations.

Office of Internal Affairs.

Mid-Atlantic Area Office.[10]

Midwest Area Office.[11]

Northeast Area Office.[12]

Pacific Area Office.[13]

Southeast Area Office.[14]

Southwest Area Office.[15]

CENTER FOR VETERINARY MEDICINE.[16]

Office of the Center Director.

Office of Management.

Management Services Staff.

Information Resources Management Staff.

Office of New Animal Drug Evaluation.

Division of Therapeutic Drugs for Food Animals.

Division of Biometrics and Production Drugs.

Division of Therapeutic Drugs for Non-Food Animals.

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[10] Mailing address: 900 U.S. Customhouse, Second Chestnut St., Philadelphia, PA 19106.
[11] Mailing address: 901 Warrenville Rd., suite 360, Lisle, IL 60532.
[12] Mailing address: 850 Third Ave., Brooklyn, NY 11232.
[13] Mailing address: 13301 Clay St., Oakland, CA 94512.
[14] Mailing address: 60 Eighth St. NE., Atlanta, GA 30309.
[15] Mailing address: 7920 Elmbrook Rd., Dallas, TX 75247.
[16] Mailing address: 7500 Standish Pl., MPN–2, Rockville, MD 20855.

Division of Human Food Safety.

Division of Manufacturing Technologies.

Office of Surveillance and Compliance.

Division of Surveillance.

Division of Animal Feeds.

Division of Compliance.

Division of Epidemiology.

Office of Research.

Administrative Staff.

Division of Residue Chemistry.

Division of Animal Research.

Division of Animal and Food Microbiology.

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH.[17]

Office of the Center Director.

Equal Employment Opportunity Staff.

Office of Systems and Management.

Division of Ethics and Management Operations.

Division of Information Technology.

Division of Planning, Analysis and Finance.

Office of Compliance.

Promotion and Advertising Policy Staff.

Division of Bioresearch Monitoring.

Division of Program Operations.

Division of Enforcement A.

Division of Enforcement B.

Office of Device Evaluation.

[17] Mailing address: 9200 Corporate Blvd., Rockville, MD 20850.

Program Management Staff.

Program Operations Staff.

Division of Cardiovascular Devices.

Division of Reproductive, Abdominal, and Radiological Devices.

Division of General, Restorative, and Neurological Devices.

Division of Ophthalmic, and Ear, Nose and Throat Devices.

Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices.

Office of Science and Technology.

Division of Mechanics and Materials Science.

Division of Life Sciences.

Division of Physical Sciences.

Division of Electronics and Computer Sciences.

Division of Management, Information and Support Services.

Office of Health and Industry Programs.

Program Operations Staff.

Regulations Staff.

Staff College.

Division of Device User Programs and Systems Analysis.

Division of Small Manufacturers Assistance.

Division of Mammography Quality and Radiation Programs.

Division of Communication Media.

Office of Surveillance and Biometrics.

Issues Management Staff.

Division of Biostatistics.

Division of Postmarket Surveillance.

Division of Surveillance Systems.

Office of In Vitro Diagnostic Device Evaluation and Safety.

Division of Chemistry and Toxicology Devices.

Division of Immunology and Hematology Devices.

Division of Microbiology.

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH.[18]

Office of the Center Director.

Environmental Health and Program Assurance Staff.

Office of Research.

Technology Advancement Staff.

Division of Biochemical Toxicology.

Division of Genetic and Reproductive Toxicology.

Division of Biometry and Risk Assessment.

Division of Microbiology.

Division of Chemistry.

Division of Neurotoxicology.

Division of Veterinary Services.

Division of Molecular Epidemiology.

Office of Management.

Office of Management Services.

Division of Facilities, Engineering and Maintenance.

Division of Administrative Services.

Division of Contracts and Acquisitions.

Office of Planning, Finance and Information Technology.

Division of Planning.

Division of Financial Management.

Division of Information Technology.

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[18] Mailing address: 3900 NCTR Dr., Jefferson, AR 72079.

§ 5.1105 Chief Counsel, Food and Drug Administration.

The Office of the Chief Counsel's mailing address is 5600 Fishers Lane, rm. 6–05, Rockville, MD 20857.[1]

§ 5.1110 FDA public information offices.

(a) *Division of Dockets Management (HFA–305).* The Division of Dockets Management public room is located in rm. 1061, 5630 Fishers Lane, Rockville, MD 20852. Telephone: 301–827–6860.

(b) *Division of Freedom of Information (HFI–35).* The Freedom of Information public room is located in rm. 12A–30, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20857. Telephone: 301–827–6567.

(c) *Press Relations Staff (HFI–40).* Press offices are located in rm. 15–A07, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20857. Telephone: 301–827–6242; and at 5100 Paint Branch Pkwy., College Park, MD 20740. Telephone: 301–436–2335.

§ 5.1115 Field structure.

NORTHEAST REGION

Regional Field Office: 158–15 Liberty Ave., Jamaica, NY 11433.

Northeast Regional Laboratory: 158–15 Liberty Ave., Jamaica, NY 11433.

New York District Office: 158–15 Liberty Ave., Jamaica, NY 11433.

New England District Office: One Montvale Ave., Stoneham, MA 02180.

Winchester Engineering and Analytical Center: 109 Holton St., Winchester, MA 01890.

CENTRAL REGION

Regional Field Office: U.S. Customhouse, Second and Chestnut Sts., rm. 900, Philadelphia, PA 19106.

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[1] The Office of the Chief Counsel (also known as the Food and Drug Division, Office of the General Counsel, Department of Health and Human Services), while administratively within the Office of the Commissioner, is part of the Office of the General Counsel of the Department of Health and Human Services.

Philadelphia District Office: U.S. Customhouse, Second and Chestnut Sts., rm. 900, Philadelphia, PA 19106.

Baltimore District Office: 6000 Metro Dr., suite 101, Baltimore, MD 21215.

Cincinnati District Office: 6751 Steger Dr., Cincinnati, OH 45237–3097.

Forensic Chemistry Center: 6751 Steger Dr., Cincinnati, OH 45237–3097.

New Jersey District Office: Waterview Corporate Center, 10 Waterview Blvd., 3d floor, Parsippany, NJ 07054.

Chicago District Office: 550 West Jackson Blvd., suite 1500, South Chicago, IL 60661.

Detroit District Office: 300 River Pl., suite 5900, Detroit, MI 48207.

Minneapolis District Office: 212 Third Ave. South, Minneapolis, MN 55401.

SOUTHEAST REGION

Regional Field Office: 60 Eighth St. NE., Atlanta, GA 30309.

Southeast Regional Laboratory: 60 Eighth St. NE., Atlanta, GA 30309.

Atlanta District Office: 60 Eighth St. NE., Atlanta, GA 30309.

New Orleans District Office: 6600 Plaza Dr., suite 400, New Orleans, LA 70122.

Florida District Office: 555 Winderley, suite 200, Maitland, FL 32751.

San Juan District Office: 466 Fernandez Juncos Ave., San Juan, PR 00901–3223.

SOUTHWEST REGION

Regional Field Office: 4040 North Central Expressway, suite 900, Dallas, TX 75204.

Dallas District Office: 4040 North Central Expressway, suite 300, Dallas, TX 75204.

Denver District Office: Bldg. 20, Denver Federal Center, Sixth and Kipling Sts., P.O. Box 25087, Denver, CO 80225–0087.

Kansas City District Office: 11630 West 80th St., Lenexa, KS 66214–3338.

St. Louis Branch: 12 Sunnen Dr., suite 122, St. Louis, MO 63143–3800.

Arkansas Regional Laboratory: 3900 NCTR Rd., Bldg. 26, Jefferson, AR 72079–9502.

Southwest Import District Office: 4040 North Central Expressway, suite 300, Dallas, TX 75204.

PACIFIC REGION

Regional Field Office: 1301 Clay St., suite 1180–N, Oakland, CA 94512–5217.

San Francisco District Office: 1431 Harbor Bay Pkwy., Alameda, CA 94502–7070.

Los Angeles District Office: 19701 Fairchild, Irvine, CA 92612.

Seattle District Office: 22201 23rd Dr. SE., Bothell, WA 98021–4421.

Pacific Regional Laboratory, SW: 19701 Fairchild, Irvine, CA 92612.

Pacific Regional Laboratory, NW: 22201 23rd Dr. SE., Bothell, WA 98021-4421.

PART 7—ENFORCEMENT POLICY

■ 2. The authority citation for 21 CFR part 7 continues to read as follows:

Authority: 21 U.S.C. 321–393; 42 U.S.C. 241, 262, 263b–263n, 264.

■ 3. Section 7.45 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 7.45 Food and Drug Administration-requested recall.

(a) The Commissioner of Food and Drugs or designee may request a firm to initiate a recall when the following determinations have been made: * * *

* * * * *

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

■ 4. The authority citation for 21 CFR part 10 continues to read as follows:

Authority: 5 U.S.C. 551–558, 701–706, 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

■ 5. Section 10.1 is amended by revising paragraph (a) to read as follows:

§ 10.1 Scope.

(a) Part 10 governs practices and procedures for petitions, hearings, and other administrative proceedings and activities conducted by the Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and other laws which the Commissioner of Food and Drugs administers.

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■ 6. Section 10.3 is amended in paragraph (a) by revising the definition for ''*The laws administered by the Commissioner*'' to read as follows:

§ 10.3 Definitions.

(a) * * *

The laws administered by the Commissioner or *the laws administered by the Food and Drug Administration* means all the laws that the Commissioner is authorized to administer.

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PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 7. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

■ 8. Section 16.26 is amended by revising paragraph (a) to read as follows:

§ 16.26 Denial of hearing and summary decision.

(a) A request for a hearing may be denied, in whole or in part, if the Commissioner or the FDA official to whom authority is delegated to make the final decision on the matter determines that no genuine and substantial issue

of fact has been raised by the material submitted. If the Commissioner or his or her delegate determines that a hearing is not justified, written notice of the determination will be given to the parties explaining the reason for denial.

* * * * *

■ 9. Section 16.40 is revised to read as follows:

§ 16.40 Commissioner.

Whenever the Commissioner has delegated authority on a matter for which a regulatory hearing is available under this part, the functions of the Commissioner under this part may be performed by any of the officials to whom the authority has been delegated, e.g., a center director.

PART 21—PROTECTION OF PRIVACY

■ 10. The authority citation for 21 CFR part 21 continues to read as follows:

Authority: 21 U.S.C. 371; 5 U.S.C. 552, 552a.

■ 11. Section 21.43 is amended by revising paragraph (a)(2) to read as follows:

§ 21.43 Access to requested records.

(a) * * *

(2) Permitting the requesting individual to review the records in person between 9 a.m. and 4 p.m. at the office of the FDA Privacy Act Coordinator, at the Freedom of Information Staff public room at the address shown in § 20.30 of this chapter, or at any Food and Drug Administration field office, listed in part 5, subpart M of this chapter, or at another location or time upon which the Food and Drug Administration and the individual agree. Arrangement for such review can be made by consultation between the FDA Privacy Act Coordinator and the individual. An individual seeking to review records in person shall generally be permitted access to the file copy, except

that where the records include nondisclosable information, a copy shall be made of that portion of the records, with the nondisclosable information blocked out. Where the individual is not given a copy of the record to retain, no charge shall be made for the cost of copying a record to make it available to an individual who reviews a record in person under this paragraph.

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PART 25—ENVIRONMENTAL IMPACT CONSIDERATIONS

■ 12. The authority citation for 21 CFR part 25 continues to read as follows:

Authority: 21 U.S.C. 321–393; 42 U.S.C. 262, 263b–264; 42 U.S.C. 4321, 4332; 40 CFR parts 1500–1508; E.O. 11514, 35 FR 4247, 3 CFR, 1971 Comp., p. 531–533 as amended by E.O. 11991, 42 FR 26967, 3 CFR, 1978 Comp., p. 123–124 and E.O. 12114, 44 FR 1957, 3 CFR, 1980 Comp., 356–360.

■ 13. Section 25.5 is amended by revising paragraph (b)(5) to read as follows:

§ 25.5 Terminology.

* * * * *

(b) * * *

(5) *Responsible agency official* means the agency decisionmaker designated in the delegated authority for the underlying actions.

* * * * *

■ 14. Section 25.40 is amended by revising paragraph (e) to read as follows:

§ 25.40 Environmental assessments.

* * * * *

(e) The agency evaluates the information contained in an EA and any public input to determine whether it is accurate and objective, whether the proposed action may significantly affect the quality of the human environment, and whether an EIS or a FONSI will be prepared. The responsible agency

official examines the environmental risks of the proposed action and the alternative courses of action, selects a course of action, and ensures that any necessary mitigating measures are implemented as a condition for approving the selected course of action.

■ 15. Section 25.45 is amended by revising paragraph (a) to read as follows:

§ 25.45 Responsible agency official.

(a) The responsible agency official prepares the environmental documents or ensures that they are prepared.

* * * * *

PART 106—INFANT FORMULA QUALITY CONTROL PROCEDURES

■ 16. The authority citation for 21 CFR part 106 continues to read as follows:

Authority: 21 U.S.C. 321, 350a, 371.

■ 17. Section 106.120 is amended by revising paragraph (b) to read as follows:

§ 106.120 New formulations and reformulations.

* * * * *

(b) The manufacturer shall promptly notify the Food and Drug Administration when the manufacturer has knowledge (as defined in section 412(c)(2) of the act) that reasonably supports the conclusion that an infant formula that has been processed by the manufacturer and that has left an establishment subject to the control of the manufacturer may not provide the nutrients required by section 412(g) of the act and by regulations promulgated under section 412(a)(2) of the act, or when there is an infant formula that is otherwise adulterated or misbranded and that may present risk to human health. This notification shall be made, by telephone, to the Director of the appropriate Food and Drug Administration district office specified in part 5,

subpart M of this chapter. After normal business hours (8 a.m. to 4:30 p.m.) the FDA emergency number, 301–443–1240, shall be used. The manufacturer shall send a followup written confirmation to the Center for Food Safety and Applied Nutrition (HFS–605), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, and to the appropriate Food and Drug Administration district office specified in part 5, subpart M of this chapter.

PART 107—INFANT FORMULA

■ 18. The authority citation for 21 CFR part 107 continues to read as follows:

Authority: 21 U.S.C. 321, 343, 350a, 371.

■ 19. Section 107.50 is amended by revising paragraph (e)(2) to read as follows:

§ 107.50 Terms and conditions.

* * * * *

(e) * * *

(2) The manufacturer shall promptly notify FDA when the manufacturer has knowledge (as defined in section 412(c)(2) of the act) that reasonably supports the conclusion that an exempt infant formula that has been processed by the manufacturer and that has left an establishment subject to the control of the manufacturer may not provide the nutrients required by paragraph (b) or (c) of this section, or when there is an exempt infant formula that may be otherwise adulterated or misbranded and if so adulterated or misbranded presents a risk of human health. This notification shall be made, by telephone, to the Director of the appropriate FDA district office specified in part 5, subpart M of this chapter. After normal business hours (8 a.m. to 4:30 p.m.), the FDA emergency number, 301–443–1240, shall be used. The manufacturer shall send a followup written confirmation to the Center for Food Safety and Applied

Nutrition (HFS–605), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, and to the appropriate FDA district office specified in part 5, subpart M of this chapter.

■ 20. Section 107.230 is amended by revising paragraph (e) to read as follows:

§ 107.230 Elements of an infant formula recall.

* * * * *

(e) The recalling firm shall furnish promptly to the appropriate Food and Drug Administration district office listed in part 5, subpart M of this chapter, as they are available, copies of the health hazard evaluation, the recall strategy, and all recall communications (including, for a recall under § 107.200, the notice to be displayed at retail establishments) directed to consignees, distributors, retailers, and members of the public.

■ 21. Section 107.240 is amended by revising paragraphs (b) and (c)(1) to read as follows:

§ 107.240 Notification requirements.

* * * * *

(b) *Method of notification*. The notification made pursuant to § 107.240(a) shall be made, by telephone, to the Director of the appropriate Food and Drug Administration district office listed in part 5, subpart M of this chapter. After normal business hours (8 a.m. to 4:30 p.m.), FDA's emergency number, 301–443–1240, shall be used. The manufacturer shall send written confirmation of the notification to the Center for Food Safety and Applied Nutrition (HFS–605), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, and to the appropriate Food and Drug Administration district office listed in part 5, subpart M of this chapter.

(c) * * * (1) *Telephone report*. When a determination is made that an infant formula is to be recalled, the recalling firm shall telephone within 24 hours the appropriate Food and Drug Administration district office listed in part 5, subpart M of this chapter and shall provide relevant information about the infant formula that is to be recalled.

* * * * *

■ 22. Section 107.250 is amended by revising the introductory paragraph to read as follows:

§ 107.250 Termination of an infant formula recall.

The recalling firm may submit a recommendation for termination of the recall to the appropriate Food and Drug Administration district office listed in part 5, subpart M of this chapter for transmittal to the Center for Food Safety and Applied Nutrition (HFS–605), for action. Any such recommendation shall contain information supporting a conclusion that the recall strategy has been effective. The agency will respond within 15 days of receipt by the Center for Food Safety and Applied Nutrition (HFS–605), of the request for termination. The recalling firm shall continue to implement the recall strategy until it receives final written notification from the agency that the recall has been terminated. The agency will send such a notification unless it has information, from FDA's own audits or from other sources, demonstrating that the recall has not been effective. The agency may conclude that a recall has not been effective if:

* * * * *

PART 203—PRESCRIPTION DRUG MARKETING

■ 23. The authority citation for 21 CFR part 203 continues to read as follows:

Authority: 21 U.S.C. 331, 333, 351, 352, 353, 360, 371, 374, 381.

■ 24. Section 203.11 is amended by revising paragraph (a) to read as follows:

§ 203.11 Applications for reimportation to provide emergency medical care.

(a) Applications for reimportation for emergency medical care shall be submitted to the director of the FDA District Office in the district where reimportation is sought (addresses found in part 5, subpart M of this chapter).

* * * * *

PART 500—GENERAL

■ 25. The authority citation for 21 CFR part 500 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 353, 360b, 371.

■ 26. Section 500.80 is amended by revising paragraph (a) to read as follows:

§ 500.80 Scope of this subpart.

(a) The Federal Food, Drug, and Cosmetic Act requires that sponsored compounds intended for use in food-producing animals be shown to be safe and that food produced from animals exposed to these compounds be shown to be safe for consumption by people. The statute prohibits the use in food-producing animals of any compound found to induce cancer when ingested by people or animals unless it can be determined by methods of examination prescribed or approved by the Secretary (a function delegated to the Commissioner of Food and Drugs) that no residue of that compound will be found in the food produced from those animals under conditions of use reasonably certain to be followed in practice. This subpart identifies the steps a sponsor of a compound shall follow to secure the approval of the compound. FDA guidance documents contain the procedures and protocols FDA recommends for the implementation of this subpart. These guidance

documents are available from the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests for these guidance documents should be identified with Docket No. 1983D–0288.

* * * * *

PART 800—GENERAL

■ 27. The authority citation for 21 CFR part 800 continues to read as follows:

Authority: 21 U.S.C. 321, 334, 351, 352, 355, 360e, 360i, 360k, 361, 362, 371.

■ 28. Section 800.55 is amended by revising paragraph (g)(4) to read as follows:

§ 800.55 Administrative detention.

* * * * *

(g) * * *

(4) The presiding officer of a regulatory hearing on an appeal of a detention order, who also shall decide the appeal, shall be a regional food and drug director (i.e., a director of an FDA regional office listed in part 5, subpart M of this chapter) who is permitted by § 16.42(a) of this chapter to preside over the hearing.

* * * * *

PART 1002—RECORDS AND REPORTS

■ 29. The authority citation for 21 CFR part 1002 continues to read as follows:

Authority: 21 U.S.C. 352, 360, 360i, 360j, 360hh–360ss, 371, 374.

■ 30. Section 1002.3 is revised to read as follows:

§ 1002.3 Notification to user of performance and technical data.

The Director and Deputy Director of the Center for Devices and Radiological Health, as authorized under delegated authority, may require a manufacturer of a radiation emitting electronic product to provide to the ultimate purchaser, at the time of original purchase, such performance data

and other technical data related to safety of the product as the Director or Deputy Director finds necessary.

Dated: March 29, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

Note: This appendix will not appear in the Code of Federal Regulations.

APPENDIX A—PART 5; CORRESPONDING FORMER SUBPARTS, SECTION NUMBERS, AND SUBJECTS AND NEW ALTERNATE INTERNET-BASED SYSTEM FDA STAFF MANUAL GUIDE NUMBERS

Former CFR Subpart, Section No., and Subject	Alternate Internet-Based System FDA Staff Manual Guide (SMG) Numbers (Subject remains, unless otherwise stated)
Subpart Key: Subpart A, § 5.10 to § 5.19—Delegations of Authority to the Commissioner Subpart B, § 5.20 to § 5.99—General Redelegations of Authority Subpart C, § 5.100 to § 5.199—Human Drugs; Redelegations of Authority Subpart D, § 5.200 to § 5.299—Biologics; Redelegations of Authority Subpart E, § 5.300 to § 5.399—Foods and Cosmetics; Redelegations of Authority Subpart F, § 5.400 to § 5.499—Medical Devices and Radiological Health; Redelegations of Authority Subpart G, § 5.500 to § 5.599—Animal Drugs; Redelegations of Authority Subpart H, § 5.600 to § 5.699—Radiation Control; Redelegations of Authority Subpart I, § 5.700 to § 5.799—Product Designation; Redelegations of Authority Subpart J, § 5.800 to § 5.899—Imports and Exports; Redelegations of Authority Subpart K, § 5.900 to § 5.999—Orphan Products; Redelegations of Authority Subpart L, § 5.1000—Mammography Facilities; Redelegations of Authority Subpart M, § 5.1100—Organization	SMG Index: SMG 1410.10—Delegations of Authority to the Commissioner of Food and Drugs SMG 1410.20—General Redelegations of Authority SMG 1410.100—Human Drugs SMG 1410.200—Biologics SMG 1410.300—Foods and Cosmetics SMG 1410.400—Medical Devices and Radiological Health SMG 1410.500—Animal Drugs SMG 1410.600—Radiation Control SMG 1410.700—Product Designation SMG 1410.800—Imports and Exports SMG 1410.900—Orphan Products SMG 1410.1000—Mammography Facilities
Subpart A, § 5.10—Delegations From the Secretary of Health and Human Services to the Commissioner of Food and Drugs. Subpart A, § 5.11—Reservation of authority.	SMG 1410.10—Delegations of Authority to The Commissioner of Food and Drugs (Note: Paragraph 2 of this SMG contains the Reservation of Authority.)
Subpart B, § 5.20—General redelegations of authority from the Commissioner to other officers of the Food and Drug Administration.	SMG 1410.21
Subpart B, § 5.21—Emergency functions.	SMG 1410.22
Subpart B, § 5.22—Certification of true copies and use of Department seal.	SMG 1410.23
Subpart B, § 5.23—Disclosure of official records and authorization of testimony.	SMG 1410.24
Subpart B, § 5.24—Authority relating to technology transfer.	SMG 1410.25
Subpart B, § 5.25—Research, investigation, and testing programs and health information and promotion programs.	SMG 1410.26—Research, Investigation, and Testing Programs and Health Promotion Programs
Subpart B, § 5.26—Service fellowships.	SMG 1410.27
Subpart B, § 5.27—Patent term extensions for human drug products, medical devices, and food and color additives; and authority to perform due diligence determinations and informal hearings.	SMG 1410.18
Subpart B, § 5.28—Hearings.	SMG 1410.29
Subpart B, § 5.29—Petitions under part 10.	SMG 1410.30—Petitions Under Title 21, Code of Federal Regulations (21 CFR), Part 10
Subpart B, § 5.30—Authority to select temporary voting members for advisory committees and authority to sign conflict of interest waivers.	SMG 1410.31
Subpart B, § 5.31—Enforcement activities.	SMG 1410.32
Subpart B, § 5.32—Certification following inspections.	SMG 1410.33
Subpart B, § 5.33—Issuance of reports of minor violations.	SMG 1410.34
Subpart B, § 5.34—Issuance of notices relating to proposals and orders for debarment and denial of an application to terminate debarment.	SMG 1410.35
Subpart B, § 5.35—Officials authorized to make certification under 5 U.S.C. 605(b) for any proposed and final rules.	SMG 1410.36
Subpart C, § 5.100—Issuance of notices implementing the provisions of the Drug Amendments of 1962.	SMG 1410.101
Subpart C, § 5.101—Termination of exemptions for new drugs for investigational use in human beings.	SMG 1410.102
Subpart C, § 5.102—Authority to approve and to withdraw approval of a charge for investigational new drugs.	SMG 1410.103
Subpart C, § 5.103—Approval of new drug applications and their supplements.	SMG 1410.104
Subpart C, § 5.104—Responses to Drug Enforcement Administration temporary scheduling notices.	SMG 1410.105

APPENDIX A—PART 5; CORRESPONDING FORMER SUBPARTS, SECTION NUMBERS, AND SUBJECTS AND NEW ALTERNATE INTERNET-BASED SYSTEM FDA STAFF MANUAL GUIDE NUMBERS—Continued

Former CFR Subpart, Section No., and Subject	Alternate Internet-Based System FDA Staff Manual Guide (SMG) Numbers (Subject remains, unless otherwise stated)
Subpart C, § 5.105—Issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and their supplements.	SMG 1410.106
Subpart C, § 5.106—Submission of and effective approval dates for abbreviated new drug applications and certain new drug applications.	SMG 1410.107
Subpart C, § 5.107—Extensions or stays of effective dates for compliance with certain labeling requirements for human prescription drugs.	SMG 1410.108
Subpart C, § 5.108—Authority relating to waivers or reductions of prescription drug user fees.	SMG 1410.109
Subpart C, § 5.109—Issuance of written notices concerning patent information, current good manufacturing practices and false or misleading labeling of new drugs.	SMG 1410.110
Subpart D, § 5.200—Functions pertaining to safer vaccines.	SMG 1410.201
Subpart D, § 5.201—Redelegation of the Center for Biologics Evaluation and Research Director's program authorities.	SMG 1410.202
Subpart D, § 5.202—Issuance of notices of opportunity for a hearing on proposals for denial of approval of applications for licenses, suspension of licenses, or revocation of licenses and certain notices of revocation of licenses.	SMG 1410.203
Subpart D, § 5.203—Issuance and revocation of licenses for the propagation or manufacture and preparation of biological products.	SMG 1410.204
Subpart D, § 5.204—Notification of release for distribution of biological products.	SMG 1410.205
Subpart E, § 5.300—Food standards, food additives, generally recognized as safe (GRAS) substances, color additives, nutrient content claims, and health claims.	SMG 1410.301—Food Standards, Food Additives, Generally Recognized As Safe (GRAS) Substances, Color Additives, Nutrient Claims, and Health Claims
Subpart E, § 5.301—Issuance of initial emergency permit orders and notices of confirmation of effective date of final regulations on food for human and animal consumption.	SMG 1410.302
Subpart E, § 5.302—Detention of meat, poultry, eggs, and related products.	SMG 1410.303
Subpart E, § 5.303—Establishing standards and approving accrediting bodies under the National Laboratory Accreditation Program.	SMG 1410.304
Subpart E, § 5.304—Approval of schools providing food-processing instruction.	SMG 1410.305
Subpart F, § 5.400—Issuance of Federal Register documents to recognize or to withdraw recognition of a standard to meet premarket submission requirements.	SMG 1410.401
Subpart F, § 5.401—Issuance of Federal Register documents pertaining to exemptions from premarket notification.	SMG 1410.402—Issuance of Federal Register Documents Pertaining to Premarket Submission Requirements and Exemption from Premarket Notification
Subpart F, § 5.402—Detention of adulterated or misbranded medical devices	SMG 1410.403
Subpart F, § 5.403—Authorization to use alternative evidence for determination of the effectiveness of medical devices.	SMG 1410.404
Subpart F, § 5.404—Notification to petitioners of determinations made on petitions for reclassification of medical devices.	SMG 1410.405
Subpart F, § 5.405—Determination of classification of devices.	SMG 1410.406
Subpart F, § 5.406—Notification to sponsors of deficiencies in petitions for reclassification of medical devices.	SMG 1410.407
Subpart F, § 5.407—Approval, disapproval, or withdrawal of approval of product development protocols and applications for premarket approval for medical devices.	SMG 1410.408
Subpart F, § 5.408—Determinations concerning the type of valid scientific evidence submitted in a premarket approval application.	SMG 1410.409
Subpart F, § 5.409—Determinations that medical devices present unreasonable risk of substantial harm.	SMG 1410.410
Subpart F, § 5.410—Orders to repair or replace, or make refunds for, medical devices.	SMG 1410.411
Subpart F, § 5.411—Medical device recall authority.	SMG 1410.412

APPENDIX A—PART 5; CORRESPONDING FORMER SUBPARTS, SECTION NUMBERS, AND SUBJECTS AND NEW ALTERNATE INTERNET-BASED SYSTEM FDA STAFF MANUAL GUIDE NUMBERS—Continued

Former CFR Subpart, Section No., and Subject	Alternate Internet-Based System FDA Staff Manual Guide (SMG) Numbers (Subject remains, unless otherwise stated)
Subpart F, § 5.412—Temporary suspension of a medical device application.	SMG 1410.413
Subpart F, § 5.413—Approval, disapproval, or withdrawal of approval of applications and entering into agreements for investigational device exemptions.	SMG 1410.414
Subpart F, § 5.414—Postmarket surveillance.	SMG 1410.415
Subpart F, § 5.415—Authority relating to medical device reporting procedures.	SMG 1410.416
Subpart F, § 5.416—Medical device tracking.	SMG 1410.417
Subpart F, § 5.417—Authority pertaining to accreditation functions for medical devices.	SMG 1410.418
Subpart G, § 5.500—Issuance of Federal Register documents pertaining to the determination of safe levels, notice of need for development of an analytical method, notice of availability of a developed analytical method, and prohibition of certain extralabel drug use.	SMG 1410.501
Subpart G, § 5.501—Approval of new animal drug applications, medicated feed mill license applications and their supplements.	SMG 1410.502
Subpart G, § 5.502—Issuance of notices, proposals, and orders relating to new animal drugs and medicated feed mill license applications.	SMG 1410.503
Subpart G, § 5.503—Submission of and effective approval dates for abbreviated new animal drug applications and certain new animal drug applications.	SMG 1410.504
Subpart G, § 5.504—Issuance of written notices concerning patent information, current good manufacturing practices and false or misleading labeling of new animal drugs and feeds bearing or containing new animal drugs.	SMG 1410.505
Subpart G, § 5.505—Termination of exemptions for new drugs for investigational use in animals.	SMG 1410.506
Subpart H, § 5.600—Variances from performance standards for electronic products.	SMG 1410.601
Subpart H, § 5.601—Exemption of electronic products from performance standards and prohibited acts.	SMG 1410.602
Subpart H, § 5.602—Testing programs and methods of certification and identification for electronic products.	SMG 1410.603
Subpart H, § 5.603—Notification of defects in, and repair or replacement of, electronic products.	SMG 1410.604
Subpart H, § 5.604—Manufacturers requirement to provide data to ultimate purchasers of electronic products.	SMG 1410.605
Subpart H, § 5.605—Dealer and distributor direction to provide data to manufacturers of electronic products.	SMG 1410.606
Subpart H, § 5.606—Acceptance of assistance from State and Local authorities for enforcement of radiation control legislation and regulations.	SMG 1410.607
Subpart I, § 5.700—Authority relating to determination of product primary jurisdiction.	SMG 1410.701
Subpart I, § 5.701—Premarket approval of a product that is or contains a biologic, a device, or a drug.	SMG 1410.702
Subpart J, § 5.800—Imports and exports.	SMG 1410.801
Subpart J, § 5.801—Export of unapproved drugs.	SMG 1410.802
Subpart J, § 5.802—Manufacturer's resident import agents.	SMG 1410.803
Subpart K, § 5.900—Orphan products.	SMG 1410.901
Subpart L, § 5.1000—Authority to ensure that mammography facilities meet quality standards.	SMG 1410.1000
Subpart M—Organization	(Note: Subpart M will remain in the CFR and it is updated in this final rule.)

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